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December 20, 2004

Food & Drug Administration
Division of Dockets Management
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504
RIN number 0910-AC14

RE: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production

Daybreak Foods, a major producer of eggs and raw liquid egg products takes a proactive approach in quality assurance and food safety programs. This includes farm programs addressing food safety such as egg handling, chemical control, pest control and biosecurity. We welcome the opportunity to comment on this proposal for the Prevention of *Salmonella* Enteritidis in Shell Eggs During Production. We are requesting the FDA consider Daybreak's input as well as documents submitted by other producers and industry groups. As a result of this consideration we would ask that the FDA revise the standing proposal to address these concerns and resubmit the document for an additional public comment period.

ASSUMPTIONS ABOUT EGG BASED SALMONELLA OUTBREAKS

The background information published with this rule does not appear to be the most recent available. As a result, we believe the occurrence of SE in eggs has been overstated. In addition, it would appear from the information provided in the background section of the rule did not adequately consider other ingredients in the foods identified as causing Salmonella outbreaks. A broad range of foods, vegetables, cheeses and even dried oat cereals have been shown to be affected by Salmonellosis. Daybreak Foods believes that every food should be stored and handled in a safe manner and we believe that education and monitoring the effectiveness by industrial preparation and consumers is an integral part of assuring a safe food supply. In a farm-to-table approach the preparation point immediately prior to serving the food is truly the most critical.

VACCINATED FLOCKS

Allowances should be made in compliance standards for vaccinated flocks. Vaccinations have been shown to be an effective control point of SE mitigation programs. Incentives, such as reduced testing and recordkeeping requirements, should be provided to help producers offset the cost of vaccinating the flocks and the drop in productivity as a result of the vaccination.

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We believe this rule should be revised giving consideration to programs such as vaccination which have decreased the likelihood of Salmonella in the flocks.

SE NEGATIVE PULLET SUPPLY

With the enactment of this rule, egg producers may request proof of SE negative pullets from the growers. Pullet growers will need time to adapt and to meet the needs of the layer industry. The proposed one year implementation would not allow for the phase in of grower based programs. A two year implementation timeline is more realistic.

MANURE HANDLING

We contend the focus of the regulation should be on results rather than on methodologies. Producers should be able to use other methods to control SE rather than have a mandated 100% manure removal program in the case of a SE positive flock.

Weather and crop cycles dictate when manure can be land applied. Layer flocks are moved out at all times of the year. In some instances manure storage buildings would need to be built in order to comply with the 100% removal of manure between flocks. Storage buildings can cost 100's of thousands of dollars, depending on the capacity requirements, zoning, EPA and DNR regulations. Permitting procedures along with financial considerations in terms of building loan acquisitions and the like will be costly and time consuming.

In addition, many producers feel that 100% manure removal increases insect control issues. This is counterproductive to the on farm SE control programs.

WET CLEANING OF LAYER BUILDINGS

Wet cleaning may do little more then to upset the competitive exclusion conditions that exist naturally in the layer facilities. Data exists showing wet cleaning to be ineffective, if not a contributing factor to SE positive environments. Layer facilities have not been engineered and built to be effectively wet cleaned. Numerous considerations may need to be made for employee safety during this activity.

The FDA model does not accurately reflect the cost to producers for wet cleaning during cold weather or the preparation time needed prior to wet cleaning. We request that the wet cleaning requirement be removed.

TRAINING REQUIREMENTS

This regulation specifies that the SE program responsible party has been trained adequately as defined by the FDA. The industry will need time to hire and train employees who can administer these programs. A 2-3 day training session plus travel

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time will be very costly for the producers and difficult to handle by a 7 day work week schedule.

The training needs to be available now if we have any hope as an industry to be able to meet the proposal timeline. Once people are in place, systems of record keeping will have to be put together, audited and corrective actions put into effect.

COOLER MODIFICATION

Many producers will need to adapt cooler capacity in order to meet 45 degree cooling requirements. In addition, refrigerated trailers will need to be secured. Excess capacity in the transportation industry is extremely limited at this point in time. In years when the egg market is already depressed these issues can put a significant strain on the producer finances.

REGULATORY LANGUAGE

We find this regulation to be overly prescriptive.

The industry should not be instructed on how to clean livestock buildings or when to change clothing or have specific pest controls measures mandated.

Today's best intentions can be tomorrow's folly. It is a problem we live with in the egg products industry every day. We MUST not repeat the same mistakes again. The focus needs to remain SE negative egg supply. Producers should be able to make the decisions appropriate to their specific situations.

DEFINITION OF A BIOSECURITY PROGRAM

The regulation's biosecurity definition mandates that all layer buildings on the same site be considered under the same biosecurity program. Some farms are configured so that there are several separate distinct buildings or sets of buildings. In addition examples already exist where specific buildings can and are being targeted to separate markets.

A better solution would be for the producer to define the biosecurity program at each site and then comply with that program.

TESTING REQUIREMENTS

Can the contract lab industry absorb the demand of the egg industry? Some independent labs avoid the analysis of heavily loaded media such as the manure swabs as a matter of reducing the risk of cross contamination between samples.

Producers should be able to set up their own testing laboratories if desired. So called rapid testing methods on the farm should be allowed as long as the producing farm can show that their results are accurate, for example, by a documented training for the person(s) performing the tests.

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Qualitative testing, a simple positive or negative result, should be acceptable. Unless the rule is revised to accept a certain level of SE, quantitative testing may not be useful. Language should be provided for in the rule to accommodate changes to current "official" methods for future advances.

COORDINATION OF ACTIVITIES

With the proposal of the creation of the Food Safety Administration (FSA) we believe it would be prudent for the FDA to combine efforts with the USDA on this subject.

There has been much effort directed toward research and data collection by the USDA. We would ask that this effort be completed prior to mandating compliance standards so that we might take advantage of the knowledge to be gained from the USDA and as a result put together a better regulation.

Also, the USDA has decided to disregard much of the earlier data (prior to 1999). We believe that this is prudent and believe that the public would be best served if the FDA would also. Regulations should be based on the best, most recent data available.

MARKET FORCES

The agency has predicted a level of SE positive flocks once tests begin. This may result in an over supply of eggs to the breaker market and potentially an under supply to the shell egg market. Only a few major breakers are set up to received eggs from off site producers. Can the breaker market absorb the excess capacity and will the government support the prices of the diverted stock to counteract the effect of this rule?

Is the FDA prepared to require processors to accept eggs from positive flocks as breaking stock?

We believe that the costs to producers are understated primarily in the cost of diversion and in the failure of the model to appreciate the impact of the non-productive time in the facility at the time and in the administration of the program.

EGG STORAGE

We believe the 36 hour maximum hour time is unnecessarily restrictive. The predictive model used to set this recommendation was not well anchored to actual data points. We concur with the UEP position that a graduated time and temperature plan would effective.

IMPLEMENTATION TIME LINE

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We support a two year implementation as one which is more realistic. Many of the comments made in this document support this point. Implementation of the act as it stands now will be difficult and potentially prohibitively expensive to accomplish.

PROGRAM ADMINSTRATION

Registration of location and size of facilities: Mandating this information could have FOI implications and could result in the decrease of security at the producer sites. The FDA has other means at its disposal to learn the site information needed to administer this program and still respect the needs for security at the producer sites.

Annual Site Visits: Producers have numerous and varied biosecurity requirements. They must be assured that inspectors will abide by their standing biosecurity policies such as not bringing personal effects to the site, shower-in-shower-out and respecting the time required between visiting from on site to the next even though they may exceed FDA minimums.

Record Duplication: It is not necessary to copy documents during the inspection process. The inspector can review documents on site and compliance can be determined as a result of this review. The producers' right to privacy should not be subjugated the agency's proposal for copies to ease the completion of reports.

Inspection Agencies: We strenuously **oppose** the proposal that unnamed local authorities may be designated to perform inspections. We agree with the UEP position that AMS is capable to perform these duties.

Thank you for the opportunity to comment on this rule. We look forward to cooperative spirit that will serve the public and support the efforts for continual improvement.

Sincerely,

Patricia Stonger
Director, Quality Assurance